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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,301	REITER ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-26 and 63, drawn to a molecule comprising an antibody specifically bindable with an HLA class I/antigen and composition thereof, classified in Class 530, subclass 391.1 and Class 424, subclass 178.1.

Note Absent evidence to the contrary, each of the recited molecules/composition thereof is distinct since each ligands(s) to which each of said molecules is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 1-26 and 63 encompass hundreds of GROUPS, not species.

It is noted that the instant claims encompass a specific molecule comprising an antibody specifically bindable with an HLA class I/antigen and composition thereof. Applicant is required to elect a specific molecule comprising an antibody specifically bindable with a specific HLA/antigenic peptide combination, such as a molecule comprising an antibody with the sequence of SEQ ID NO: 9 specifically bindable with HLA-A2.1/SEQ ID NO: 2 (gp100 peptide G9-209M, IMDQVPFSV).

II. Claims 27-37, 62 and 64, drawn to a molecule comprising a polynucleotide encoding an antibody specifically bindable with an HLA class I/antigen and composition thereof, classified in Class 536, subclass 23.53.

Note Absent evidence to the contrary, each of the recited molecules is distinct since each ligands(s) to which each of said molecules is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 27-37, 62 and 64 encompass hundreds of GROUPS, not species.

It is noted that the instant claims encompass a specific nucleic acid molecule encoding an antibody specifically bindable with an HLA class I/antigen and composition thereof. Applicant is required to elect a specific nucleic acid molecule encoding an antibody specifically bindable with a specific HLA/antigenic peptide combination, such as a nucleic acid molecule with the sequence of SEQ ID NO: 8 that encodes an antibody with the sequence of SEQ ID NO: 9 specifically bindable with HLA-A2.1/SEQ ID NO: 2 (gp100 peptide G9-209M, IMDQVPFSV).

III. Claims 38-44, drawn to a method of producing an antibody specifically bindable with an HLA class I/antigen comprising immunizing a transgenic mammal with a soluble MHC/class I peptide complex, classified in Class 800, subclass 6.

IV. Claims 45-47, drawn to a method of treating a cancer comprising administering a molecule comprising an antibody specifically bindable with an HLA class I/antigen, classified in Class 424, subclass 181.1.

V. Claims 48-50, drawn to a method of treating a viral infection comprising administering a molecule comprising an antibody specifically bindable with an HLA class I/antigen, classified in Class 424, subclass 183.1.

VI. Claims 51-53, drawn to a method of treating an autoimmune disease comprising administering a molecule comprising an antibody specifically bindable with an HLA class I/antigen, classified in Class 424, subclass 179.1.

VII. Claims 54, 55 and 59, drawn to a method of making an immunotoxin comprising ligating a polynucleotide encoding an antibody specifically bindable with an HLA class I/antigen in frame with a polynucleotide encoding a toxin moiety, classified in Class 435, subclass 69.7.

VIII. Claims 56-58, drawn to a method of making an immunolabel comprising ligating a polynucleotide encoding an antibody specifically bindable with an HLA class I/antigen in frame with a polynucleotide encoding an identifiable moiety, classified in Class 435, subclass 70.1.

IX. Claims 60 and 61, drawn to a method of detecting the presence and/or level of APC presenting an HLA-restricted antigen in a sample of cells, classified in Class 435, subclasses 7.24 and 325.

2. The GROUPS encompassed by (I) vs (II) are different products.

Nucleic acids and proteins are distinct because their structures are different, which require non-coextensive searches

3. Inventions III-IX are different methods.

These inventions require different ingredients and process steps to accomplish the use of treating different diseases with different etiologies and endpoints for treatment such as cancer (Invention IV) or a viral infection (Invention V) or an autoimmune disease (Invention VI) using an antibody, producing an antibody in a transgenic animal by immunizing said animal with an HLA/peptide antigen complex (Invention III), making an antibody-immunotoxin molecule using recombinant means with a polynucleotide (Invention VII), making an antibody-immunolabel molecule (different molecule from the immunotoxin molecule of Invention VII)

using recombinant means with a polynucleotide (Invention VIII), or detecting the presence and/or level of APC presenting an HLA-restricted antigen in a sample of cells using an antibody and reacting said antibody with APC.

4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

6. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

7. Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an immunogen.

8. Inventions VII and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can

be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the product as claimed can be made by conjugating a protein to a toxin moiety by chemical after-treatment.

9. Inventions VIII and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the product as claimed can be made by conjugating a protein to a label by chemical after-treatment.

10. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the product as claimed can be made by immunization of non-transgenic mammals and recombinant means.

Therefore they are patentably distinct.

11. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IX is not required for any other group from Groups I-IX and Groups I-IX have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are

not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. **If Applicant elects one of the Groups encompassed by (I)**, Applicant is further required to (1) elect a single disclosed species (a ***specific identifiable moiety***, for example, one of the single disclosed species recited in claim 6 such as an enzyme) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

14. **If Applicant elects one of the Groups encompassed by (II)**, Applicant is further required to (1) elect a single disclosed species (a ***specific identifiable moiety***, for example, one of the single disclosed species recited in claim 32 such as an enzyme) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

15. **If Applicant elects the Invention of Group III** Applicant is further required to (1) elect a single disclosed species of antibody to be produced *and* a single chain MHC molecule to be used in the claimed method (a ***specific SEQ ID NO***, for example SEQ ID NO: 9 and a specific soluble HLA/b2m/peptide single chain construct, for example HLA-A2.1/SEQ ID NO: 2) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

16. **If Applicant elects one of the Inventions of Group IV, V or VI,** Applicant is further required to (1) elect a single disclosed species of molecule to be used in the claimed method of treatment comprising a specific antibody *and* a specific therapeutic moiety (a ***specific antibody***, for example, SEQ ID NO: 9 and a cytotoxic moiety) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

17. **If Applicant elects one of the Inventions of Group VII or VIII,** Applicant is further required to (1) elect a single disclosed species of polynucleotide molecule to be used in the claimed method, said polynucleotide molecule encoding a specific antibody, *and* a second polynucleotide molecule encoding a toxin moiety (for Group VII) or a specific identifiable moiety (for Group VIII) (a ***specific antibody***, for example, SEQ ID NO: 9 encoding SEQ ID NO: 8 and an enzyme) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

18. **If Applicant elects one of the Inventions of Group IX,** Applicant is further required to (1) elect a single disclosed species of antibody to be used in the claimed method *and* a specific APC presenting a specific HLA/antigenic peptide combination (a ***specific antibody***, for example, SEQ ID NO: 9 and HLA-A2.1/SEQ ID NO: 2) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

19. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

20. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

22. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

23. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

24. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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